

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

16023987

Applicant information:

Date Prepared:	November 25, 2002
Name:	CONTAMAC Ltd.
Address:	Bearwalden Business Park Saffron Walden Essex England CB11 4JX
Contact Person:	Robert McGregor
Phone number:	44-1799 542 000
US Agent:	Medvice Consulting, Inc. Martin Dalsing
Phone number:	(970) 243-5490
Fax number:	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	CONTAFLEX 38 (polymacon) Spherical Soft Contact Lens for Daily Wear (clear and tinted, lathe-cut)

**Equivalent Devices:**

The CONTAFLEX 38 (polymacon) Spherical Soft Contact Lenses are substantially equivalent to the following predicate device

Predicate device:

“BENZ 38”

Manufactured/distributed by Benz Research and Development.

510(k) number; **K961103**

Device Description:

The CONTAFLEX 38 Spherical Soft Contact Lenses are fabricated from polymacon, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The nonionic lens material, (polymacon) is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA), cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polymacon and 38% water by weight when immersed in normal buffered saline solution. The lens is available in clear and with a blue visibility-handling tint, [phthalocyaninato (2-)] copper. The polymacon name has been adopted by the United States Adopted Names Council (USAN).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The (polymacon) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of the lens are:

Refractive Index	1.438 (hydrated)
Light Transmission (clear)	greater than 94%
Light Transmission (tinted)	greater than 94%
Water Content	38 % \pm 2%
Specific Gravity	1.170
Oxygen Permeability	7.93×10^{-11} (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fatt method).

**Intended Use:**

The **CONTAFLEX 38 (polymacon) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The lens may be disinfected using a chemical disinfecting system.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Description of Safety:

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the CONTAFLEX 38 Soft Contact Lens material. The results of all testing demonstrated that the safety and effectiveness of the CONTAFLEX 38 Soft Contact Lens is equivalent to the currently marketed Benz polymacon contact lens material. A summary of these results from the preclinical studies is presented below.

Toxicology:

In-Vitro Cytotoxicity: ISO 10993-5 was conducted in accordance with standards on test article. The test article meets the requirements of the Agarose Overlay Method.

Systemic Toxicity: The lens material meets the requirements of the systemic injection test and is considered non-toxic.

Acute Ocular Irritation: Acute ocular irritation test was performed and produced no ocular irritation.

Shelf Life

Shelf life requirements are satisfied via referencing rights granted to Contamac Ltd. for 510(k) 973597. The data presented supports substantial equivalence of this CONTAFLEX 38 Soft Contact Lens material to the already marketed Benz polymacon.

Substantial Equivalence:

The CONTAFLEX 38 Soft Contact Lens is substantially equivalent to the predicate device as depicted in the following table, and does not raise different questions of safety and effectiveness than the predicate device identified previously.

The following table depicts the pre-clinical characteristics of the CONTAFLEX 38 material, as well as the predicate device.



Substantial Equivalence table

	Pre-Clinical equivalency / Device	CONTAFLEX 38 (polymacon)	BENZ 38 (polymacon)
1.)	Intended Use	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
2.)	Functionality	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
3.)	Indications	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
4.)	Production Method	Lathe-cut	Lathe-cut
5.)	FDA Group #	Group # 1 <50% Water, nonionic Polymers	Group # 1 <50% Water, nonionic Polymers
6.)	USAN name	polymacon	polymacon
7.)	Water Content	40.4%	39.0%
8.)	Oxygen Permeability	7.93 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35 degrees C), (revised Fatt method).	7.61 X 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35 degrees C), (revised Fatt method).
9.)	Specific Gravity	1.170	1.169



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2003

Contamac, Ltd.
c/o Martin Dalsing
Regulatory Consultant and U.S. Agent for Contamac. Ltd.
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K023987
Trade/Device Name: CONTAFLEX 38 (polymacon) Spherical Soft Contact Lens for
Daily Wear (clear and tinted, lathe-cut)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lenses
Regulatory Class: Class II
Product Code: LPL
Dated: November 25, 2002
Received: December 2, 2002

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Martin Dalsing

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

Device Name: **CONTAFLEX 38 (polymacon) Spherical Soft Contact Lens for Daily Wear (clear and tinted, lathe-cut)**

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Concurrence of CDRH Office of Device Evaluation (ODE)

Walter W. C. Brown, Ph.D.
(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

J
Prescription Use X
(Per 21 CFR 801.109)

510(k) Number or K023987

Over-The-Counter Use

(Optional Format 1-2-96)